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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,269	09/23/1999	RANDALL S. ALBERTE	CEA-004.01	9298

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EXAMINER

YAMNITZKY, MARIE ROSE

ART UNIT	PAPER NUMBER
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1774

DATE MAILED: 08/27/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/405,269

Applicant(s)

ALBERTE ET AL.

Examiner

Marie R. Yamnitzky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64, 66-74 and 89-91 is/are pending in the application.
- 4a) Of the above claim(s) 27, 28 and 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26, 29-33, 38-64, 66-74 and 89-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. This Office action is in response to applicants' amendment filed June 04, 2003 (Paper No. 16), which amends the specification, amends claims 1, 27, 29, 31, 33, 39, 42, 44, 45, 48, 49, 52-54, 56-58, 61-63, 67, 69 and 70, cancels claims 65 and 75-88 and adds claims 89-91. (Claim 69 is notated as an original claim, but it is not the same as claim 69 as originally filed.)

Claims 1-64, 66-74 and 89-91 are pending.

2. Applicants' arguments filed June 04, 2003 have been fully considered when making the rejections set forth in this Office action.

New rejections not necessitated solely by applicants' amendment are made in this Office action. Accordingly, this action is not made final.

3. The claims remain subject to an election of species. In Paper No. 11, applicants elected the species of a compound of general structure 1, applied to the surface of a medical device, wherein X represents -OH, Y represents O and Z represents an optionally substituted aryl. Of the pending claims, claims 1-26, 29-33, 38-64, 66-74 and 89-91 read on the elected species. (Claims dependent from claim 39 which further limit the article are all considered to read on the elected species since, for claims 39 and dependents, the article pertains to the intended use of the claimed coating.)

Claims 27, 28 and 34-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

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4. The disclosure is objected to because of the following informalities:

Lines 13 and 14 on page 10 refer to R_9 and R_8 "as defined above" and line 23 on page 10 also refers to R_8 as defined above, but no definition of R_9 and R_8 precedes these portions of the specification.

Page 11, line 25 references a prior definition of R_8 but no definition is set forth prior to this portion of the specification.

Page 12, line 2 references prior definitions of R_9 and R_{10} but no definitions of these variables are set forth prior to this portion of the specification.

Line 6 of page 24 states " R_{41} is as defined above" but there is no definition of R_{41} preceding this portion of the specification.

Appropriate correction is required.

5. Claims 1-5, 7-13, 16, 17, 19-22, 25, 26, 29-33, 38-43, 45-51, 54, 55, 57-60, 63, 63, 66-74 and 89-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 1 and 39 have been amended to limit any substituent for Z to a Markush group of possibilities. Support is provided for most of the recited Markush group members by the specification at page 11, lines 9-22, p. 13, l. 5-10 and p. 17, l. 25-29. However, the examiner does not find support for "acyl" or "alkoxycarbonyl". If applicants are of the

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position that these Markush group members are supported by the application is originally filed, applicants are respectfully requested to identify support by referencing page and line number(s).

6. Claim 64 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails how describe how to make a “permanent” coating comprising an effective amount of an anti-fouling compound represented by general structure 1 wherein the coating releases the compound when in contact with a surface of an article. As the compound is released, the content of the compound will decrease until such time as there is no more compound of general structure 1 in the coating, at which time the coating comprising the compound no longer exists. It is unknown how such a coating could ever be considered to be a “permanent” coating.

7. Applicants’ arguments filed June 04, 2003 regarding the rejection of claim 64 under 35 U.S.C. 112, first paragraph, have been fully considered but they are not persuasive.

A compound represented by general structure 1 is a required component of the claimed coating. If a coating does not comprise the compound, a coating does not meet the limitations of claim 39, with claim 64 dependent therefrom.

8. Claims 1-26, 29-33, 38-64, 66-74 and 89-91 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific systems and coatings demonstrated by the examples to have anti-fouling capabilities as required by the present claims, does not reasonably provide enablement for a system comprising a surface comprising a compound selected from the myriad of compounds encompassed by the present claims, or a coating comprising a compound selected from the myriad of compound encompassed by the present claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In light of the specification, the terms "system" and "biofilm resistant surface" encompass a very large group of articles/surfaces including such disparate "systems" as food processing equipment, heart valves, tampons and toilets. For example, see page 5, lines 8-17, p. 9, l. 5-7, p. 15, l. 16, p. 15, l. 26-p. 16, l. 2, p. 16, l. 23-p. 17, l. 10, p. 18, l. 6-14, p. 18, l. 20-p. 19, l. 10 and p. 25, l. 9-p. 26, l. 27. In light of claim 29, it appears that the presently claimed system even encompasses plants.

In light of the specification, the term "coating" encompasses gas, vapor, liquid, paste, semi-solid or solid, examples of which include polishes, surface cleaners, caulks, adhesives, finishes, paints, waxes and polymerizable compositions (e.g. see p. 14, l. 19-22).

In light of the specification, an anti-fouling compound is one that impairs, inhibits, prevents or retards the attachment and/or growth of organisms such as bacteria, fungi, viruses and protists (e.g. see p. 12, l. 16-18, p. 13, l. 23-24 and p. 18, l. 15-19).

The compounds as defined in the present claims encompass numerous compounds.

Accordingly, the present system claims encompass objects as diverse as food processing equipment, heart valves, tampons and toilets, and the present coating claims encompass any gas, vapor, liquid, paste, semi-solid or solid, wherein the system or coating comprises at least one compound selected from the myriad of compounds encompassed by the general structures defined in the claims that would impair, inhibit, prevent or retard the attachment and/or growth of organisms such as bacteria, fungi, viruses and/or protists. Clearly, the claims are extremely broad. Even in the case where the compounds are more limited as in the case of present claim 22, the claims are still broad because limitations such as the "effective amount" are defined only in reference to a variety of potential applications.

The present specification provides data demonstrating anti-fouling capabilities of only a few compounds within the scope of the present claims, and demonstrates the anti-fouling characteristics of only a few systems and coating. The limited data presented in the specification are insufficient to demonstrate any predictability with respect to how each of the numerous compounds encompassed by the general structures defined in the present claims would function in an anti-fouling capacity against any one of thousands of possible organisms such as bacteria, fungi, viruses and/or protists if used in/on any one of the numerous possible diverse surfaces/ systems contemplated by the present specification and encompassed by the present claims. Accordingly, it is the examiner's position that it would require undue experimentation on the part of one of ordinary skill in the art at the time of the invention to make and use the invention commensurate in scope with the present claims.

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9. Claims 1-26, 29-33, 38-64, 66-74 and 89-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of Z is not clear because Z as further defined in some of the present pending claims is not consistent with Z as defined in the present independent claims. Claims 5, 43 and several other dependent claims allow Z to represent optionally substituted heteroalkylphenyl. It is not clear how heteroalkylphenyl or substituted heteroalkylphenyl fit within the definition of Z as set forth in the dependent claims. Claims 5, 43 and several other dependent claims also allow Z to be optionally substituted alkylphenyl, arylphenyl or heteroarylphenyl. While it is clear that alkylphenyl, arylphenyl or heteroarylphenyl are within the scope of Z as defined in the independent claims, it is not clear how substituted alkylphenyl, substituted arylphenyl and substituted heteroarylphenyl are within the scope of Z as defined in the independent claims. Claims 6, 44 and several other dependent claims allow Z to represent 4-(1-methyl-1-phenylethyl)phenyl but it is not clear how this possibility meets the limitations of Z as set forth in the independent claims.

The limitations imposed by claims 31 and 67 are not clear. It is not clear if the biofilm resistant surface in the case of claim 31 and the coating in the case of claim 67 must be in the form of a liquid or gas since "ml" is conventionally used with respect to liquids and gases, and not with solids.

The scope of a "permanent" coating as required by claim 64 is not clear since claim 39, from which claim 64 depends, requires the compound to be releasable from the coating.

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10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 39-42, 44-49, 52-54, 56-58, 61-63, 66, 68-73 and 89-91 are rejected under 35 U.S.C. 102(b) as being anticipated by The Merck Index, Tenth Ed. (1983), pp. 876-877.

The only ingredient explicitly required for the coating of claim 39 and dependents is the compound represented by general structure 1. General structure 1 as defined in present claim 39, with claims 40-42, 44-49, 52-54, 56-58, 61-64, 66, 68-74 and 89-91 dependent therefrom, encompasses methyl sulfate. As taught at page 14, line 20, of the specification, "coating" can be a gas, vapor, liquid, paste, semi-solid or solid. Also, as specifically recited in claim 70, the coating may have many different forms.

The Merck Index discloses that methyl sulfate is an oily liquid that is soluble in water and alcohol. Accordingly, methyl sulfate meets the limitations of a coating consisting of a compound represented by general structure 1 as defined in claim 39, with claims 40-42, 44-49, 52-54, 56-58, 61-63, 66, 68-74 and 89-91 dependent therefrom.

Since methyl sulfate is within the scope of a compound represented by general structure 1, and the present specification specifically discloses methyl sulfate as suitable for the present invention, it is the examiner's position that it is reasonable to expect that methyl sulfate, if

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applied to a surface of an article, would be released so as to impair biofilm formation on the surface.

With respect to the release rate set forth in claim 66, the release rate is not a characteristic of the coating per se, but a characteristic of the coating in a particular use situation. The present specification teaches a wide variety of articles to which the coating may be applied, including articles such as scalpels, heart valves, food processing equipment, tampons and toilets. For example, see page 25, line 13-p. 26, l. 27. A coating composition applied to one article and used under a specific set of environmental conditions, such as applied to a toilet bowl, will not necessarily exhibit the same release rate as the same composition applied to a different article that is used under a different set of environmental conditions, such as applied to a heart valve. Accordingly, the release rate specified in claim 66 is not considered to patentably distinguish methyl sulfate as disclosed in The Merck Index from methyl sulfate which may be the sole component of the claimed coating.

With respect to claims 71-73 and 89-91, the identity of the article to which the coating may be applied, and the intended use of the article to which the coating may be applied, does not place any positive limitations on the coating per se. Further with respect to claim 91, it is the examiner's position that it is reasonable to expect that methyl sulfate per se would provide the effect set forth in the claim since methyl sulfate is specifically disclosed in the present specification as a suitable compound for the present invention.

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 39-64, 66-74 and 89-91 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-58 and 65-78 of copending Application No. 09/405,299. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a coating with the only positively recited component of the coating being a compound. In the case of the present claims, the compound is represented by general structure 1. In the case of the copending claims, the compound is represented by general structure 1, 2 or 3. There is substantial overlap between the compounds represented by general structures 1, 2 and 3 as defined in the copending claims and general structure 1 as defined in the present claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Applicant is advised that should claim 68 be found allowable, claim 69 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an

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application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

15. Any inquiry concerning this communication should be directed to Marie R. Yamnitzky at telephone number (703) 308-4413. The examiner works a flexible schedule but can generally be reached at this number from 6:30 a.m. to 4:00 p.m. Monday, Tuesday, Thursday and Friday, and every other Wednesday from 6:30 a.m. to 3:00 p.m.

The current fax number for Art Unit 1774 is (703) 872-9306 for all official faxes. (Unofficial faxes to be sent directly to examiner Yamnitzky can be sent to (703) 872-9041.)

MRY
August 25, 2003



MARIE YAMNITZKY
PRIMARY EXAMINER

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